



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,674	03/23/2001	Beat Muller	CL/V-31362A	5772

1095 7590 03/20/2003

THOMAS HOXIE
NOVARTIS, PATENT AND TRADEMARK DEPARTMENT
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

WILSON, DONALD R

ART UNIT	PAPER NUMBER
----------	--------------

1713

DATE MAILED: 03/20/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,674

Applicant(s)

MULLER ET AL.

Examiner

D. R. Wilson

Art Unit

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1713

DETAILED ACTION

Response to Restriction Requirement

1. Applicant's election of the inventions of Group II, Claims 1-9, in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 10-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Election of Species Requirement

2. Applicant's election of the prepolymer prepared from:
- a. dimethylacrylamide (DMA) as the hydrophilic monomer,
 - b. crosslinker of Example 1 as the crosslinker,
 - c. cysteamine hydrochloride as the chain transfer agent having a functional group, and
 - d. acryloyl chloride as the functional group reactive organic compounds having an ethylenically unsaturated group,
- in the same Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Applicant's election of the crosslinker of Example 1 was unclear because Example 1 discloses several cross-linkers. During a telephone conversation with Mr. Robert J. Gorman on 3/13/03 a provisional election was made the crosslinker of Example 1a, i.e., the diacrylamide of di-aminopropyl terminated polydimethylsiloxane, was elected as the specie of crosslinker. Affirmation of this election must be made by applicant in replying to this Office action.

Claim Rejections - 35 USC § 112, First Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1713

5. **Claims 1- are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prepolymers, wherein the chain transfer reagent has a functional group in addition to the chain transfer group, and wherein said functional group is then converted to a group having ethylenic unsaturation by reaction with a compound having an ethylenically unsaturated group, does not reasonably provide enablement for prepolymers wherein the chain transfer agent does not have such groups, and wherein the reaction in step (b) does not result in attachment of an ethylenically unsaturated group to the prepolymer.** The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification only teaches the use of functional chain transfer agents which in addition to the chain transfer group contain a functionality for subsequent conversion to a polymerizable or crosslinkable group. It is not seen that the inventive compositions without this functionality, such as are within the scope of the current claims, are enabled. The current claims also include reactions in step(b) which do not result in conversion of a functional group to a polymerizable or crosslinkable group, e.g., protonation by an unsaturated acid, or addition of the functional group across the double bond.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. **Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**
8. The language of Claim 1 is indefinite because of use of the term "is obtainable" making it unclear as to whether or not the prepolymer is obtained. This can be overcome by using the definite language "is obtained".
9. The languages of Claims 1-4 are indefinite because "hydrophilic" is a relative term the metes and bounds of which cannot be determined. The Examiner acknowledges the characterization of hydrophilic

Art Unit: 1713

monomers at page 2, second paragraph, of the specification. However, this description only says what they typically are in terms of water solubility, and further does not include the conditions of water solubility, e.g., hot or cold water would be expected to produce different results.

10. The language of Claim 2 is unclear because of the number of nested Markush groups, some of which are in the wrong form, and the inconsistent punctuation, particularly at the end of R₃ is (i).

When materials recited in a claim are so related as to constitute a proper Markush group, they should be recited in the conventional manner, or in the alternative. For example, "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, or alternatively, "wherein R is A, B, C or D" is also proper. See M.P.E.P. § 2173.05(h).

Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. (See 37 U.S.C. § 1.75 (i).)

The claim needs to be rewritten using proper Markush language and making the nesting of groups clear by the use of indentation and/or punctuation.

11. Claim 3 is indefinite because of an improper Markush group. This can be overcome by inserting "the group consisting of" following "from" in the third line of text.

Claim Rejections - 35 USC § 102(b)/§ 103(a)

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1713

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. **Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai'729.**

16. Lai'729 discloses novel cross-linking agents to prepare curable hydrophilic copolymer for use in applications such as contact lenses (col. 1, lines 14-18). A preferred crosslinker is a polyorganosiloxane of formula III having terminal ester or amide groups of (meth)acrylic acid (col. 7, lines 36-65), which encompasses the elected specie of crosslinker. A polydimethylsiloxane would readily have been envisaged as this is the only polyorganosiloxane exemplified. It would have been obvious to one of ordinary skill in the art to employ the instantly elected specie of diacrylamide of di-aminopropyl terminated polydimethylsiloxane with an expectation of equivalent results to the other cross-linkers of Formula III. It is also disclosed that monomer systems for hydrogel lenses employ a hydrophilic monomer of which N,N-dimethylacrylamide is one of the specifically listed preferred monomers, which makes its use readily envisaged (col. 6, line 63 to col. 7, line 8, col. 10, lines 42-63, col. 11, lines 3-15). The use of prepolymers capped with (meth)acrylate or (meth)acrylamide is also taught (col. 11, lines 15-22). It would have been obvious that such capping of prepolymers would have to be done on functional end-groups in the prepolymers, and that such functional groups would need to arise either from an initiator or chain-transfer agent. In regards to the specific compounds used as a chain transfer agent or as an end-capping agent to impart acrylate or acrylamido end caps, it is not seen that the elected species in the product-by-process aspect of the instant product claim imparts a significant difference in the product being claimed. The amount of cross-linking agent is taught not to exceed 20 wt.%, with preferred narrower ranges (col. 13, lines 23-36), and it is not seen that the relative amounts of chain transfer agent, cross-linking agent and hydrophilic monomer are outside of what would be found to be operable amounts obvious to one of ordinary skill in the art and determined by routine experimentation.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233; *In re Reese* 129 USPQ 402.

17. **Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as anticipated by, and in the alternative Claim 8 is also rejected under 35 U.S.C. 103(a) as being unpatentable, over Jung.** (Jung

Art Unit: 1713

is the US equivalent to DE'343 cited by applicant.) Although not directed to the elected species of the invention, this rejection is included in order to advance prosecution and because the reference is an equivalent to a reference cited by applicant.

18. Jung discloses an acrylate copolymer with free double bonds produced by the reaction of a precrosslinked acrylate resin (A) and a compound containing at least one unsaturated polymerizable bond (B) (Claim 1). The precrosslinked resin (A) is not gelled and is formed from a monomer (a) having at least two polymerizable double bonds an amount of 3 to 30 wt.% a crosslinker), 5 to 60 wt.% of a functional monomer (b), and at least 0.5 wt.% of a polymerization regulator (col. 1, line 57 to col. 2, line 12). Functional monomers (b) include a number of monomers which would be considered to be hydrophilic (col. 3, lines 8-30). Polymerization regulators disclosed include mercapto compounds containing an additional functional group such as hydroxyl or carboxyl, and it would have been readily envisaged to use such (col. 6, lines 23-39). When the functional monomer (b) has a hydroxyl functional group, compound (B) is taught to be for instance to react with acrylate esters by transesterification or with acrylic acid (col. 3, line 31-66). Relative amounts of chain transfer agent, crosslinker and hydrophilic monomer such as are instantly claimed are seen to be envisioned by one of ordinary skill in the art, or in the alternative would have been obvious from the teachings of the reference.

Objection to Title

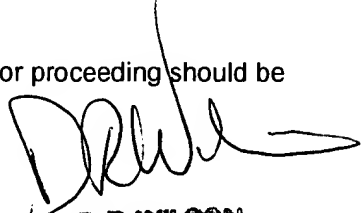
19. The title of the invention is too generic and not descriptive of the claimed invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. R. Wilson whose telephone number is 703-308-2398.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 703-308-2450. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications. The unofficial direct fax phone number to the Examiner's desk is 703-872-9029.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-2351.


D.R. WILSON
PRIMARY EXAMINER